

510(k) Summary**MAR 22 2013**

Applicant:	Spineology Inc. 7800 3 rd Street N., Suite 600 Saint Paul, MN 55128 Phone: 651-256-8500 Fax: 651-256-8505
Contact Person:	Bryan Becker
Date Prepared:	November 21, 2012
Trade Name:	Rampart O and Rampart P
Product Classification and Code:	Class II Medical Device, Product Code MAX, 21 CFR 888.3080
Predicate Device(s):	Spineology PEEK Lumbar Interbody Fusion Devices (K111880, K113030, and K120293)
Device Description:	The Spineology Rampart O and P Devices are designed for use with autograft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The device is available in a range of lengths and heights. The device and associated instruments are provided non-sterile.
Intended Use:	<p>The Rampart O and P Devices are an intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.</p> <p>These devices may be implanted singly or in pairs via an open or a minimally invasive posterior or transforaminal approach.</p> <p>The Rampart O and P Devices are designed for use with autograft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.</p>
Purpose of this 510(k):	The purpose of this 510(k) is to add devices as small as 20 mm in length and add products that include features that allow for rotation of the devices after insertion on implants with tantalum markers.
Summary of Technological Characteristics:	The device is shown to be substantially equivalent to the intended use, materials, configuration, and performance characteristics of the predicate products.

Testing	The Rampart O and P Devices were tested in compliance with FDA's guidance document titled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device". Preclinical testing according to ASTM F2077, including static compression and static compression shear. This testing demonstrated similar performance characteristics to the identified predicate devices.
Conclusion:	The information submitted in this premarket notification supports a determination that the Spineology Rampart O and P Devices are substantially equivalent in technological characteristics and intended use to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 22, 2013

Spineology, Incorporated
% Mr. Bryan Becker
Regulatory Affairs Manager
7800 3rd Street North, Suite 600
Saint Paul, Minnesota 55128

Re: K123652

Trade/Device Name: Rampart O and Rampart P
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 20, 2012
Received: March 8, 2012

Dear Mr. Becker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Rampart O and Rampart P**Indications for Use:**

Rampart O and Rampart P are intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

These devices may be implanted singly or in pairs via an open or a minimally invasive posterior or transforaminal approach.

Rampart O and Rampart P are designed for use with autograft as an adjunct to fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices